REMARKS

The paragraph starting on page 26, line 34 of the specification has been amended to correct obvious punctuation and syntax errors. No new matter is added.

Claims 1-6, 9, 10, 12-18, 54 and 60 are currently pending in the application. Claims 1-6, 9, 10 and 12-18 are canceled without prejudice to Applicants' rights, and Applicants specifically reserve the right, to prosecute these claims in this or a related application. New claims 61-68 are added. Upon entry of the present amendment, claims 54 and 60-68 will be pending.

Claim 54 is amended to recite that the claimed placenta is bloodless and perfused. Claim 60 is amended to depend from claim 54. Support for the amended and new claims may be found in the previously-pending claims, the claims as originally filed, and in the specification as follows:

54	Section 5.4 (generally); specifically, page 26, lines 20-21;
61	Page 18, line 11;
62	Page 14, lines 3-5; page 16, line 20; Example 6.2.2;
63	Page 14, lines 2-3; page 16, lines 21-23;
64	Page 17, line 25 to page 18, line 5; page 27, lines 26-34;
65	Page 14, lines 1-3;
66	Section 5.4;
67	Page 21, line 10; and
68	Section 5.4.

No new matter is added by new claims 61-68. Additionally, because the amended and new claims are directed to subject matter that has already been considered, no new search of the prior art is required.

The Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 1-6, 9, 10, 12-18, 54 and 60 under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of "ABC-p^+". Applicants respectfully traverse.

Applicants point out that claims 1-6, 9, 10, and 12-18 have been canceled. The Examiner's rejection of these claims on this basis is therefore moot. Moreover, claim 54 did not, and as amended does not, recite "ABC-p"; thus, the rejection of this claim on this basis is inappropriate. Applicants respectfully request the Examiner withdraw the rejection of claim 54 on this basis.

New claim 67 recites "ABC-p". The Examiner no longer contends that "ABC-p$^+$" could mean "antibodies bound/cell," "antibody binding capacity" or "placenta ABC protein." (*see* Paper No. 12, Office Action mailed August 28, 2003). Rather, the Examiner now contends that:

> During an interview on 3/9/04, subsequent to the response, the inventor Dr. Hariri clarified that "ABC-p" refers to the ABC transporter protein family. As such, a survey of the art of record indicates that the surface markers widely used for identifying ABC transporters are MDR, bcrp1, ABCG2, or their gene product P-glycoprotein (p-gp) and BCRP [citing references], "ABC-p" does not appear to be a widely accepted marker, and the specification fails to define the marker if it differs from the well-known MDR, BCRP and ABCG2, and thus, the metes and bounds of the claims could not readily be determined.

Applicants submit that a misunderstanding occurred in the 3/9/04 interview regarding the definition of "ABC-p". In that interview, Dr. Hariri referred the Examiner to the paper Leonard *et al.*, "The Role of ABC Transporters in Clinical Practice," *The Oncologist* 8:411-424 (2003), which discloses and discusses a family of transporter proteins known as "ABC" proteins. Leonard *et al.* relates to one specific ABC transporter, the ABC-p transporter, which is highly expressed in the placenta. (*See* Leonard *et al.*, p. 413, left column, last line to right column, first line; *see also* Lorkowski & Cullen, "ABCG Subfamily of Human ATP-Binding Cassette Proteins," *Pure Appl. Chem.* 74(11):2057-2081 (2002), particularly pp. 2057 (abbreviations) and 2068, last full paragraph; note that ABCP has several *synonyms*, such as BCRP, MRX and ABCG2. The Leonard *et al.* and Lorkowski & Cullen references are attached hereto for the Examiner's convenience.). It is this transporter to which the claim's recitation of "ABC-p" refers.

It is thus clear from Leonard *et al.* that "ABC-p" refers to one protein (*i.e.*, one marker). Persons of skill in the art would understand that "ABC-p" refers to a specific transporter protein of the ABC family, and that the synonyms BCRP, MRX and ABCG2 refer to the same transporter. Claims, such as claim 67, that recite "ABC-p" are therefore not indefinite by virtue of the recitation.

The Rejection under 35 U.S.C. § 102(b) Over Sanders

The Examiner has rejected claims 1-6, 9, 10, 12-18 and 60 under 35 U.S.C. § 102(b) as anticipated by Sanders *et al.*, U.S. Patent No. 3,862,002; the Examiner cites Larsson *et al.*, *Angiogenesis* 5:107-110 (2000) and Kurtzberg *et al.*, *New Engl. J. Med.* 335:157-166 (1996) in support of this rejection.

For a reference to anticipate, the reference must disclose each and every limitation of the claim to which it is compared. *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304 (Fed. Cir. 2002); *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292 (Fed. Cir. 2002)

Applicants have canceled claims 1-6, 9, 10 and 12-18 without prejudice, reserving the right to pursue these claims in this or a related application; thus, the rejection as to these claims is moot. Applicants respectfully request that the Examiner withdraw the claim rejections on this basis. Claim 60 has been amended to depend from claim 54. The Examiner acknowledges the novelty of claim 54 in view of Sanders *et al.*, as this claim was rejected over Sanders *et al.*; thus, Sanders *et al.* does not anticipate new claims 60-68, all of which depend from claim 54.

The Rejection Under 35 U.S.C. § 102(b) Over Muhlemann *et al.*

The Examiner has rejected claims 1-5, 10, 12-14 and 16-18 under 35 U.S.C. § 102(b) as anticipated by Muhlemann *et al.*, *Placenta* 16:367-373 (1995). The Examiner states that "as long as the placenta taught by Muhlemann et al. is from a mammalian, has been isolated, exsanguinated, and perfused in a sterile medium, it meets claim limitation." Office Action, page 7.

Applicants have canceled claims 1-5, 10, 12-14 and 16-18 without prejudice, reserving the right to pursue these claims in this or a related application; thus, the rejection as to these claims is moot. Applicants respectfully request that the Examiner withdraw the rejection of claims 1-5, 10, 12-14 and 16-18 on this basis. The Examiner acknowledges the novelty of claim 54 over Muhlemann *et al.*, as the claim was not rejected over Muhlemann *et al.*; thus, Muhlemann *et al.* does not anticipate new claims 60-68, all of which depend from claim 54.

The Rejection of Claim 54 Under 35 U.S.C. § 102(b) over Ordi *et al.*

The Examiner has rejected claim 54 under 35 U.S.C. § 102(b) over Ordi *et al.*, *Am. J. Surg. Pathol.* 8:1006-1011 (1998). Ordi allegedly relates to a study of placentas infected with malaria. The placentas of Ordi are not treated in any way, let alone perfused; thus, Ordi does not teach the claimed placentas, which are bloodless and perfused.

While the claim amendments render the rejections of the Examiner moot, Applicants take this opportunity to respectfully correct a misunderstanding on the part of the Examiner. The Examiner states that the present claim, directed to a placenta in which a cell is "engrafted" is essentially a product-by-process claim, and, as such, the process step (*i.e.*,

engrafting) does not further limit the claimed placenta. The Examiner further states that "the parasite cells [*i.e.*, malarial cells] established their growth in the placenta (engrafted with a cell) . . ." From this assertion, it is apparent that the Examiner misunderstands the term "engrafted." No one of skill in the art speaks of a cell, present in a tissue as the result of infection, as "engrafted" within that tissue. Infecting cells infect; they do not engraft. In the context of claim 54, for example, "engrafted" indicates clearly that the presence of the recited cell within the placenta is deliberate, and that the combination of placenta and cell is a man-made creation.

Nevertheless, Applicants have amended claim 54 to recited that the claimed placenta is bloodless and perfused, and *comprises* a cell not of fetal or maternal origin. As above, Ordi *et al.* does not teach,disclose, or suggest a bloodless placenta. As such, Ordi does not teach the claimed invention, a "bloodless, perfused placenta" comprising a cell; thus, Ordi *et al.* cannot possibly anticipate claim 54 as amended. The Examiner is respectfully urged to withdraw the rejection of this claim on this basis. Additionally, because claim 54 is not anticipated by Ordi *et al.*, Ordi *et al.* does not anticipate any of new claims 60-68.

The Double Patenting Rejection

The Examiner has provisionally rejected claims 1, 6, 9 and 10 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending application no. 10/074,976. Applicants have canceled claims 1, 6, 9 and 10 without prejudice to their right to pursue these claims in this or a related application. The double patenting rejection of these claims is thus moot, and Applicants respectfully request the Examiner withdraw the rejection of these claims on this basis.

Conclusion

For the reasons provided above, the claims as amended, and new claims, should now be in condition for allowance, and early notice of the same is earnestly solicited. No new search of the prior art is required to assess patentabilty of the claims. Applicants believe that no fee is due for this Amendment. However, if a fee should be deemed due, please charge such fee to Jones Day deposit account no. 503013.

Respectfully submitted,

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